

REMARKS

The Office Action dated May 21, 2009 has been received and reviewed. Prior to the present communication, claims 1, 2, 6-12, 15-17, 20, 24, and 27 were pending in the subject application. Claims 6, 7, 11, 15, 16, 24, and 27 have been canceled herein, and each of claims 1, 12, 17 and 20 has been amended. Claims 30-32 have been added. As such, claims 1, 2, 8-10, 12, 17, 20, and 30-32 remain pending. Applicants submit that no new matter has been added by way of these amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Allowable Subject Matter

Applicants would like to thank the Examiner for pointing out allowable subject matter in claims 11, 12, 17, and 20. Claim 1 has been amended to incorporate the subject matter of claim 11. Additionally, independent claim 30 includes the subject matter of claims 11 and 12 and independent claim 32 includes the subject matter of claims 11 and 20. Accordingly, independent claims 1, 30, and 32 are believed to be in condition for allowance. Claims 2, 6-10, 12, 17, and 20 depend from independent claim 1. Claims 2, 6-10, 12, 17, and 20 are believed to be in condition for allowance at least because of their dependency. *See, In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *see also*, MPEP § 2143.01.

Objections to Claims

Claims 6 and 7 have been objected to as being of improper dependent form for failing to limit the subject matter of a previous claim. Claims 6 and 7 have been canceled by way of the present communication, thus, rendering the rejection of these claims moot.

Double Patenting

Claims 24 and 27 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-2 of co-pending Application No. 2004/0033537. Claims 24 and 27 have been canceled by way of the present communication and, accordingly, the rejection of these claims has been rendered moot.

Claim 24 has been provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-14 of U.S. Patent No. 7,192,724. Claim 24 has been canceled by way of the present communication and, accordingly, the rejection of this claim has been rendered moot.

Claims 1-3, 6-12, 15-17 and 20 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-3 and 7-14 of co-pending Application No. PG-pub 2004, 0126898. Claims 3, 11, 15, and 16 have been canceled by way of the present communication and, accordingly, the rejection of these claims has been rendered moot. Regarding the provisional non-statutory obviousness-type double patenting rejection of claims 1, 2, 6-10, 12, 17, and 20, Applicants are submitting herewith a Terminal Disclaimer to overcome the double patenting rejection.

Rejections based on 35 U.S.C. § 102

A. Applicable Authority.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . .

claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP §2131.

B. Anticipation Rejections Based on the Guerrant Reference (U.S. Patent 5,124,252).

Claim 24 has been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,124,252 to Guerrant et al. Claim 24 has been canceled by way of the present communication and, accordingly, the rejection of this claim has been rendered moot.

C. Anticipation Rejections Based on the Fine Reference (*American Journal of Gastroenterology*, Vol. 93, No. 8, pp 1300-1305, 1998).

Claims 24 and 27 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Fine et al. (*American Journal of Gastroenterology*, Vol. 93, No. 8, pp 1300-1305, 1998. Claims 24 and 27 have been canceled by way of the present communication and, accordingly, the rejection of these claims has been rendered moot.

Rejections based on 35 U.S.C. § 103

Claims 1-3, 6-10, 24, and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al., *The American Journal of Gastroenterology*, Vol. 95, No. 2, 359-367, 2000 (hereinafter “the Nielsen reference”), in view of Targan et al., *Journal of Immunology*, 1995, Vol. 155, Issue 6, 3262-3267, 1995 (hereinafter “the Targan reference”), and Fine, PG – Pub 2001/0036639A1, filing date March 2, 2001 (hereinafter “the Fine reference”). Claims 3, 6, 7, 24, and 27 have been canceled by way of the present communication, thus, rendering rejection of these claims moot. Claim 1 has been amended to include subject matter indicated as allowable by the Examiner. Thus, Applicants respectfully request withdrawal of the 35 U.S.C. 103(a) rejection of claim 1.

New Claims

Independent claims 30 and 32 are directed to methods for testing fecal samples from persons for diagnosis. The methods include, in part, obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome, diluting the sample, creating a treated sample, creating a readable sample, determining an optical density of the readable sample, determining that the sample contains an elevated level of lactoferrin, and measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA). Upon determining that the sample has an elevated level of anti-*Saccharomyces cerevisiae* antibodies and not an elevated level of anti-neutrophil cytoplasmic antibodies, the patient is diagnosed with Crohn's disease. In contrast, upon determining that the sample has an elevated level of anti-neutrophil cytoplasmic antibodies and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, the patient is diagnosed with ulcerative colitis. Independent claims 30 and 32 include subject matter indicated as allowable by the Examiner. Thus, independent claims 30 and 32 are believed to be in condition for allowance.

CONCLUSION

For at least the reasons stated above, claims 1, 2, 8-10, 12, 17, 20, and 30-32 are believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or alindsey@shb.com (such communication via email is herein expressly granted) – to resolve the same.

Submitted herewith is a Request for Continued Examination, a request for a one-month extension of time, and an Information Disclosure Statement, along with the appropriate fees. It is believed that no additional fee is due. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required, or credit any overpayment, to Deposit Account No. 19-2112, referencing attorney docket number TLAB.100292.

Respectfully submitted,

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